AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 21. (previously presented) An autoclavable composition of an aqueous injectable terminally steam sterilized suspension in a vial sealed under nitrogen atmosphere, said suspension containing particles of a water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μm with not more than 3000 particles of 10μm or greater size and not more than 300 particles of 25 μm or greater size, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount safe for parenteral administration of a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol and mixtures thereof, the ratio of said active substance to said phospholipid surface modifier is from about 3:1 to about 5:1 and the amount of said phospholipid surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier, said composition is devoid of surfactant additives which coagulate on steam sterilization, and said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and the ratio of the amount of the active substance and the thermoprotecting agent selected to provide particle size stability during and after terminal steam sterlization.

Claim 22. (previously presented) An autoclavable composition of an injectable non-flocculating aqueous terminally steam sterilized suspension under nitrogen in a sealed vial, said suspension containing particles of a water insoluble or poorly soluble drug substance with a volume weighted mean particle size of up to 3 μm with not more than 3000 particles of 10μm or greater size and not more than 300 particles of 25 μm or greater size. said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount safe for parenteral administration of a pharmaceutically acceptable, water soluble

polyhydroxy thermoprotecting agent, the ratio of said drug substance to said surface modifier is about 3:1 to about 5:1, the amount of said surface modifier is in the range from about 0.2% w/w to about 5.0% w/w, and said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization, and wherein said composition is devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier and devoid of surfactant additives which coagulate on steam sterilization, and the ratio of the amount of the active substance and the thermoprotecting agent selected to provide particle size stability during and after terminal steam sterilization.

Claim 23. (previously presented) The composition of claim 21 or claim 22, wherein the suspension also includes a nonsurfactant additive to adjust osmotic pressure.

Claim 24. (previously presented) The composition of claim 21 or claim 22, wherein the suspension can be diluted with water for parenteral administration.

Claim 25. (previously presented) The composition of claim 22, wherein the polyhydroxy compound is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol, and mixtures thereof.

Claim 26. (previously presented) The composition of claim 21 or claim 22, wherein the phospholipid surface modifier is selected from the group consisting of natural phospholipids and synthetic phospholipids.

Claim 27. (previously presented) The composition of claim 26 wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

Claim 28. (previously presented) The composition of claim 22, wherein the suspension also contains a pharmaceutical excipient for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble drug substance.

Claim 29. (previously presented) The composition of claim 21. wherein the active substance is an antifungal agent.

Claim 30. (previously presented) The composition of claim 29, wherein the antifungal agent is itraconazole.

Claim 31. (previously presented) The composition of claim 21, wherein the active substance is an immunosuppressive agent.

Claim 32. (previously presented) The composition of claim 21, wherein the active substance is a sterol.

Claim 33. (previously presented) The composition of claim 32, wherein the sterol is alfaxalone.

Claim 34. (previously presented) A lyophilized or spray dried powder prepared from the composition of claim 22.

Claim 35. (currently amended) The composition according to claim 22, wherein the water-insoluble or poorly water soluble drug substance is ~~suitable~~ for either immediate release or sustained release delivery of said drug substance by parenteral administration.

Claim 36. (previously presented) The composition of claim 35, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.

Claim 37. (previously presented) The composition of claim 31, wherein the immunosuppressive agent is a cyclosporin.

Claim 38. (previously presented) An aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, from about 0.2 % w/w /w to about 5 % w/w of one or more phospholipid surface modifiers, and a pharmaceutically acceptable, water

soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, said suspension containing particles of the water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μm, with not more than 3000 particles of 10 μm or greater size and not more than 300 particles of 25 μm or greater size, wherein the ratio of the amount of the active substance to the phospholipid surface modifier and/or the thermoprotecting agent being selected so as to provide particle size stability during and after terminal steam sterilization, and the particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, and the suspension is devoid of surfactants which coagulate on steam sterilization.

Claim 39. (previously presented) An aqueous suspension comprising particles of a water insoluble or poorly soluble biologically active substance, from about 0.2 % w/w to about 5 % w/w of one or more phospholipid surface modifiers, and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, sealed in a vial under nitrogen atmosphere, said suspension containing particles of the water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μm, with not more than 3000 particles of 10 μm or greater size and not more than 300 particles of 25 μm or greater size, the ratio of the amount of the active substance to the phospholipid surface modifier and/or the thermoprotecting agent being selected to provide particle size stability during and after terminal steam sterilization wherein the particle size subsequent to terminal steam sterilization is not more than about two-fold of the volume weighted mean particle size prior to the terminal steam sterilization, wherein the suspension is substantially devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization and the suspension is devoid of surfactants which coagulate on steam sterilization.

Claim 40. (previously presented) The suspension of claim 38, wherein the pH of the suspension before terminal steam sterilization is from about 5 to about 9.

Claim 41. (previously presented) The suspension of claim 38, which also includes a non-surfactant additive to adjust osmotic pressure of the suspension.

Claim 42. (previously presented) The suspension of claim 38, which also includes an amount of a non-surfactant additive such that, on diluting the suspension with a pharmaceutically acceptable diluent suitable for parenteral administration to a pharmaceutically acceptable concentration for parenteral administration, a suitable osmotic pressure of the diluted suspension results.

Claim 43. (previously presented) The suspension of claim 38, wherein the thermoprotecting agent is selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mamsitol, and mixtures thereof.

Claim 44. (previously presented) The suspension of claim 38, wherein the one or more phospholipid surface modifiers are natural phospholipids or synthetic phospholipids.

Claim 45. (previously presented) The suspension of claim 44. wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

Claim 46. (previously presented) The suspension of claim 38, wherein the amount of the surface modifier provides a biologically active substance to surface modifier ratio of 3:1 to 5:1.

Claim 48. (currently amended) The suspension of claim 38, wherein the composition also contains a pharmaceutical excipient for opthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble ~~bioligical~~ biological active substance.

Claim 49. (previously presented) The suspension of claim 38, wherein the active substance is an antifungal agent.

Claim 50. (previously presented) The suspension of claim 49, wherein the antifungal agent is itraconazole.

Claim 51. (previously presented) The suspension of claim 38, wherein the active substance is an immuno-suppressive drug.

Claim 52. (previously presented) The suspension of claim 51, wherein the immuno-suppressive drug is a cyclosporin.

Claim 53. (previously presented) The suspension of claim 38, wherein the active substance is a sterol.

Claim 54. (previously presented) The suspension of claim 53, wherein the sterol is alfaxalone.

Claim 56. (previously presented) The suspension of claim 38, wherein the water-insoluble or poorly water-soluble biologically active substance is at a pharmaceutically acceptable concentration for either immediate release or sustained release delivery of the active substance by parenteral administration.

Claim 57. (previously presented) The suspension of claim 56, wherein the parenteral administration is intramuscular, intravenous, or subcutaneous administration.